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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,983	02/28/2001	Tom Gilchrist	8830-125	3635

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EXAMINER

YU, GINA C

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/763,983

Applicant(s)

GILCHRIST ET AL.

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7, 8, 11 and 22-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 11, 22-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                             | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Receipt is acknowledged of amendments to claims and specification filed on April 27, 2005, which were cross-mailed with the non-final Office action dated May 4, 2005. The issuance of the present Office action resets the statutory time period for reply three months from the mailing date of this action. The rejections made under 35 U.S.C § 103 (a) as indicated in the May 4, 2005 Office action are maintained for the reasons of record.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1-5, 7-8, 11, 25, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakis et al. (US 5851461) in view of Gilchrist et al. (WO 96/17595).**

Bakis et al. teach a method of producing polysaccharide foams. See col. 2, lines 40-58. Exemplified is a solution containing sodium alginate (gelling agent) and sodium dodecyl sulfate (foaming agent), which is beaten with a mixer to form foam. See Example 1. The foam is spread onto a metal tray and cross-linked with an aqueous solution containing calcium chloride (precipitant). The foam was then dried. The reference teaches in col. 4, lines 19-65, that by treating foam with an insoluble carbonate or hydrogen carbonate salt having one of more di-or tri-valent cations, the cation is crosslinked with the polysaccharide to form a dimensionally stable foam structure. The reference goes on to teach that further treatment of the crosslinked foam

with mono-valent cation is would impart a degree of solubility in the foam. See col. 4, lines 49-65. Thus, the second precipitation process as recited in Claim 1 c) to further stabilize the foam would have been obvious to one of ordinary skill in the art. The reference teaches that chitosan, a foaming gelling agent, is soluble in acid such as acetic acid. See instant claim 11. While the reference does not teach immersing the foam in a bath of precipitate, it does teaching combining the foam with the precipitate.

Regarding claim 2, it is respectfully pointed out that the gelling agent and the precipitant must have ultimately been packaged separately, as Bakis teaches them as separate ingredients that are combined. Thus, they must ultimately come from separate packages. Furthermore it is respectfully pointed out that the instant dependent claim is directed to a process of making sterile foam. Thus, the process in which the ingredients are packaged is viewed irrelevant.

Bakis fails to teach sterilization step and lacks teaching the MW of sodium alginate.

Gilchrist et al. teach foamable formulations and foams. Alginate is taught as a foamable carrier having a MW from 10,000-200,000 kDa. See pg. 5, line 15 – pg. 6, line 12; pg. 8, line 4 – pg. 9, line 16; pg. 10, lines 4-17; pg. 11, lines 7-12; pg. 12, lines 7-31.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the foams of Bakis et al. as being sterilized by gamma radiation, as taught by Gilchrist et al., because of the expectation of achieving a product that is sterile and can thus be safely, medically applied.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the alginate of Bakis as having the MW taught by Gilchrist et al. because of the expectation of achieving a polysaccharide with a MW that is suitable for forming a stable, medically useful foam.

**Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bakis et al. in view of Gilchrist et al. as applied to claims 1-5, 7-8, 11, 25, 26, and 27 above, and further in view of Kobayashi et al. (US 5641450).**

Bakis and Gilchrist fail to teach glycerine wash.

Kobayashi et al. teach a process of making a module including a polysulphonic hollow fiber membrane. A water/glycerine wash is taught as a means preventing drying and hence deterioration of a product prior to being cut to a predetermined length. See col. 4, lines 3-11.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add glycerine to the water wash of the combined references because of the expectation of achieving a foam product that does not deteriorate upon cutting.

**Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bakis et al. in view of Gilchrist et al. as applied to claims 1-5, 7-8, 11, 25, 26, and 27 above, and further in view of Kehr et al. (US 4201846).**

Bakis et al. and Gilchrist et al. are applied as discussed above. The references lack oven-drying.

Kehr et al. teach dimensionally stable polyurethane foam. The foams were microwave dried, vacuum oven dried, and then air dried for 2 days. See col. 9, line 20 – col. 10, line 12.

It would have been obvious to one of ordinary skill in the art at the time the invention was made add oven drying, as taught by Kehr et al., to the drying step of the combined references because of the expectation of achieving enhanced moisture evaporation and hence, stability of the foam. Alternatively, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substituted the oven-drying taught by Kehr et al. for the convention drying of the combined references because of the expectation of achieving similarly dried foams.

**Claims 24 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakis et al. in view of Gilchrist et al. as applied to claims 1-5, 7-8, 11, 25, 26, and 27 above, and further in view of Clare et al. (US 4693728).**

The combined references fail to teach calcium citrate.

Clare et al. teach hydrocolloid blend for controlled release of calcium ions. The reference teaches that the introduction of divalent ions into soluble alginate solutions rapidly causes gellation through the formation of mixed alginate salts. Where it is desirable to control the speed of this gellation, various methods have been proposed, such as combining calcium citrate with soluble alginate to produce calcium ions that are released over time. See col. 1, lines 5-42.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute calcium citrate for the calcium chloride of the

combined references because calcium citrate and calcium chloride are equivalent in their effect of slowly releasing metal ions from foams, and because of the expectation of achieving a method wherein lower concentrations of alginate are used to generate a given viscosity.

### ***Response to Arguments***

Applicant's arguments filed April 27, 2005 have been fully considered but they are not persuasive.

Regarding the examiner's ground of rejection that repeated crosslinking of the Bakis polysaccharide foam with di-or trivalent metal cations to make a further dimensionally stable foam structure would have been obvious, applicants argue that Bakis' teaching is limited to using monovalent metal cations to solubilize the foam. Applicants assert that the examiner is attempting to "equate" uncrosslinking a stabilized foam to convert it to a more soluble form with a second precipitation step with a di- or trivalent cations. Examiner is well aware that these two methods are not to be "equated". Rather, the rejection is based on the ground that, given the teaching of the purposes of the stabilizing the polysaccharide foam with of di-or trivalent metal ions, and of the further treatment of the foam with monovalent ions of the already treated foam, one of skill in the art would have reasonably draw the inference that the repeated treatment of the foam with di- or trivalent metal ions, instead of monovalent metal ions, would enhance the stabilization of the foam. Applicants' assert, In response to applicant's argument that "the aim of the present invention is to achieve sufficient stabilization so as to allow sterilization", the fact that applicant has recognized another

advantage which would flow naturally from following the suggestion of the prior art, i.e., sterilization, cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In this case, it is viewed obvious that repeated crosslinking procedure would result in more stable foam structure. Whether the sterilization of the foam occurs due to the repeated crosslinking or the exposure to the gamma ray, it cannot be given patentable weight because the alleged sterilization would naturally follow from practicing the method steps as taught and suggested by the prior art references.

### ***Conclusion***

No claims are allowed.

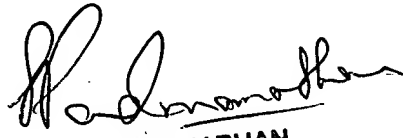
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu  
Patent Examiner



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER